MAGELLAN BIOSCIENCES

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PRODUCT RECALL NOTICE

LeadCare® Blood Lead Testing System

May 19, 2005

Dear LeadCare® User

ESA Biosciences, Inc. continuously monitors performance of its LeadCare® Test Kits. As a result of our performance monitoring program, we have discovered that, with respect to certain kits shipped between September 2003 and April 2005, a negative bias has developed over the reportable range of 1.4 ug/dl to 65ug/dl. The average negative bias has been estimated to be –26% compared to Graphite Furnace Atomic Absorption Spectroscopy (GFAAS). This exceeds ESA's accuracy claim of 95.0% agreement between LeadCare® and GFAAS at the 10 ug/dl lead threshold recommended by the CDC for retesting.

As a result of this finding, ESA is initiating a voluntary recall of the following LeadCare® Test Kits, all of which were shipped between September 2003 and April 2005.

Lot Numbers	CA6	CCA
	CA7	CCE
	CA8	CCF
	CA9	CCH

If you have received any of the listed kits, we request that you take the following action, as soon as possible:

1. Stop using affected kits.
2. Complete the attached confirmation of receipt and indicate the number of Test Kits that you require ESA to replace.

ESA will replace any un-expired kit from an affected lot at no cost to you.

If you follow the Centers for Disease Control and Prevention (CDC) guidance to retest any patient with an initial blood lead level greater than 10 ug/dl., we recommend that in addition to returning any affected kits, you retest all patients that previously tested greater than 6 ug/dl on one of the affected kits if their results were not confirmed by a method other than LeadCare®. If the results of the retest are greater than 10ug/dl, please follow your City, County and State Public Health Guidelines for elevated results.

We have taken action to prevent recurrence of this situation. We sincerely apologize for having to make this announcement and will work with you to address any concerns you may have.

Please confirm receipt of this notice by signing the attached confirmation of receipt and faxing to ESA Quality Assurance Manager at (800) 755-5095.

Please call our Blood Lead Support Group at (800) 275-0102 if you need additional assistance.

esa
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CONFIRMATION OF RECEIPT

I received the LeadCare® Blood Lead Testing System product recall notice.

_____
Name of Laboratory

_____
Address City State Zip Code

_____
Your Name (please print) Signature

_____
Date Phone Number

Please indicate below the number of kits you will need replaced. ESA will ship replacement kits along with instructions and a prepaid shipping label for returning the affected kits.

Test Kit Lot #	**Quantity**
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Fax this sheet to (800) 755-5095, Attn: ESA Quality Assurance